

Pipeline Development Status (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
sirolimus	DE-109 (STN10109)	Uveitis	Original	U.S.						
				Japan						
				Europe						
				Asia				Apr-2015		
An intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. Started an additional Phase 3 in December 2018 in the U.S. Filed for marketing approval in April 2015 in Asia.										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
tafluprost/ timolol maleate	DE-111 (STN10111)	Glaucoma/ Ocular hypertension	Co-development with AGC	China						
A fixed dose combination drug of a prostaglandin F _{2α} derivative and a beta-adrenergic receptor blocker. Launched in Japan in November 2014. Launched successively in European countries since January 2015. Launched successively in Asian countries since April 2016. Started Phase 3 in January 2019 in China.										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
omidenedapag isopropyl	DE-117 (STN10117)	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.						
				Japan					Nov-2018	
				Asia					Dec-2019	
An EP2 receptor agonist with a new mechanism of action. Started Phase 3 in September 2018 in the U.S. Launched in November 2018 in Japan. Received marketing approval in Korea in December 2019 with successive filings planned for Asian countries.										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
sepetaprost	DE-126 (STN10126)	Glaucoma/ Ocular hypertension	ONO PHARMACEUTICAL	U.S.		(Phase 2b)				
				Japan		(Phase 2b)				
A prostaglandin analogue eye drop drug product with a novel mode of action that is a dual agonist for both FP and EP3 receptors for the treatment of glaucoma and ocular hypertension. Phase 2b completed in the U.S. and Japan.										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
atropine sulfate	DE-127 (STN10127)	Myopia	Singapore Health Services, Nanyang Technological University	Japan			(Phase 2/3)			
				Asia						
Muscarinic antagonist which reduces juvenile myopia progression. Started Phase 2/3 in August 2019 in Japan. Completed P2 in April 2020 in Asia.										

—	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
glaucoma implant device	DE-128	Glaucoma	Original	U.S.				Jun-2020		
				Europe					Jan-2019	
				Asia				Mar-2020		
A drainage implant device designed to lower and sustain intraocular pressure (IOP) for the treatment of primary open-angle glaucoma through the drainage of aqueous humor. Completed Premarket Approval rolling submission to the FDA in June 2020 in the U.S. Launched in Europe in January 2019. Filed successively for marketing approval in Asian countries following Korean filing in March 2020.										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
latanoprost	DE-130A (STN10130, Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe						
				Asia						
An ophthalmic emulsion of a prostaglandin F _{2α} derivative, for the treatment of glaucoma and ocular hypertension. Started P3 trials in April 2019 in Europe and Asia.										

—	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
intraocular lens	MD-16	Cataract	Oculentis	Japan					Nov-2019	
A toric intraocular lens to treat aphakia after cataract surgery. Received manufacturing and marketing approval for Japan in November 2019.										

Changes from Q4 FY19 (May 8, 2020)

Dev. code	Changes
DE-128	Completed Premarket Approval rolling submission to the FDA in June 2020 in the U.S.

The numbering method for development codes has changed. We show both existing development codes (DE-XXX) and new development codes (STNXXXXX).